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Regulating Science: An Evaluation of the Regulation of Biotechnology Research

Part 2

by

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the federal agencies is unclear. OSTP did not cite any legal authority for its proposed Coordinated Framework in 1984, but stated that the framework would "clarify the policies of the major regulatory agencies that will be involved in reviewing research and products of biotechnology" ²⁶⁰ Clarification of policies underlying federal laws, however, rests in Congress and the courts, not in the executive branch. ²⁶¹ The Office of Management and Budget (OMB) already reviews all agency regulations. ²⁶² The additional role played by OSTP means further White House influence in regulatory decisions concerning biotechnology. ²⁶³ President Reagan approved publication of the final Coordinated Framework in the *Federal Register*; the President's approval may bind the federal agencies to abide by OSTP's coordination actions and the jurisdictional resolutions in the Coordinated Framework. ²⁶⁴

There are other problems with the Coordinated Framework. Most serious is the underlying assumption that direct release experiments of intrageneric and nonpathogenic genetically engineered organisms do not require detailed review. ²⁶⁵ The determi-

260. Proposal for a Coordinated Framework, *supra* note 236, at 50,856.

261. See generally Comments of the Environmental Policy Institute on OSTP Proposal for a Coordinated Framework for Regulation of Biotechnology, *supra* note 238, at 3. For a criticism of OSTP's and OMB's role in federal biotechnology policy, see *id.* at 2-8, 25-27.

262. See Exec. Order No. 12,291, 3 C.F.R. 127 (1982). In addition, risk management decisions by EPA are reviewed and critiqued by OMB. See *Risk Assessment Hearings*, *supra* note 94, at 297 (EPA response to committee questionnaire).

263. As mentioned earlier, risk assessment and risk management permit the intrusion of value judgments into decision making. See *supra* notes 90-110; see also Chemical Carcinogens; Review of the Science and its Associated Principles, 49 Fed. Reg. 21,594, 21,596-97 (1984) (risk assessment process is blend of science and science policy, especially when scientific uncertainties exist).

264. 22 WEEKLY COMP. PRES. DOC. 846 (June 19, 1986). The President's approval of the Coordinated Framework was probably equivalent to an order to a federal agency under the executive prerogative. See generally E. CORWIN, *THE PRESIDENT: OFFICE AND POWERS*, 1787-1984 428 n.94 (5th rev. ed. 1984). Prior to the President's authorization of the Coordinated Framework, the White House Domestic Policy Council supported and approved the BSCC. In addition, each member of the BSCC signed a Memorandum of Understanding pledging his support of the committee, as well as an agreement to abide by the committee's recommendations. *Biotechnology Development Hearings*, *supra* note 259, at 127, 137 (statement of D. Kingsbury, Chairman, BSCC).

265. Coordinated Framework, *supra* note 241, at 23,303. The preamble to the Coordinated Framework has been criticized for its failure to reflect the views of

nation may well prove to be correct, but until a predictive ecology data base is compiled, a more cautionary approach is advisable.²⁶⁶

Forum shopping may become important, aided by overlapping jurisdictions.²⁶⁷ In direct release experiments, a delay in approval may mean the difference between conducting experiments one year or the next because of climatic considerations.²⁶⁸ None of the laws under which biotechnology is being regulated were designed to regulate biotechnology. Consequently, each has deficiencies.²⁶⁹ NIH, NSF, USDA, or EPA may receive applications for direct release experiments. Not only do the boundaries of each agency's jurisdiction overlap,²⁷⁰ but gaps and gray areas exist in

ecologists. See FEDERAL REGULATION OF BIOTECHNOLOGY, *supra* note 257, at 55.

266. See *Federal Policy Could Miss Full Review of Some Harmful Products, Scientists Say*, 10 CHEM. REG. (BNA) 516, 516 (July 25, 1986) (describing criticism of Coordinated Framework by representatives of Ecological Society of America and American Society of Microbiology).

267. See 51 Fed. Reg. at 23,346 ("USDA agrees that there is the potential for overlapping jurisdiction among the Federal agencies involved in regulating biotechnology products."); see also FEDERAL REGULATION OF BIOTECHNOLOGY, *supra* note 257, at 80 (discussing conflicts between agencies in review of proposals).

Forum shopping has already occurred. While the RAC was reviewing a proposed experiment by Agracetus, the firm submitted the proposal to the USDA hoping approval would be expedited. See *Planned Releases Hearing*, *supra* note 234, at 215-16 (letter from R. Cape, Chairman, Agracetus, to Rep. Volkmer (Jan. 8 1986)). RAC delayed review because of procedural requirements of NEPA. See *id.* Under the Coordinated Framework, the USDA requires NEPA procedures to be followed, whereas the EPA does not.

268. *Planned Releases Hearing*, *supra* note 234, at 215 (letter from R. Cape, Chairman, Agracetus, to Rep. Volkmer (Jan. 8, 1986)) (protocol for test of genetically engineered tobacco plants required mid-May timing of test).

269. See ENVIRONMENTAL IMPLICATIONS REPORT, *supra* note 203, at 41 (concluding that "[n]o statute gives any agency express jurisdiction over commercial biotechnology"); Interim Report of the Federal Interagency Committee on Recombinant DNA Research: Suggested Elements for Legislation 2 (Mar. 15, 1977), cited in Barkstrom, *Recombinant DNA and the Regulation of Biotechnology: Reflections on the Asilomar Conference, Ten Years After*, 19 AKRON L. REV. 81, 92 & n.46 (1985) (interagency committee of 18 agencies concluded that existing statutes did not adequately cover regulation of biotechnology research). For example, under the Toxic Substances Control Act, 15 U.S.C. § 2602(2)(A) (1982), the definition of chemical substance may not cover genetically engineered organisms. Under the Federal Plant Pest Act, 7 U.S.C. § 150aa(c) (1982), harm must be caused to plants by genetically engineered organisms for the Act to apply.

270. See Coordinated Framework, *supra* note 241, at 23,303. To date OSHA has not issued biotechnology regulations. OSHA, adopting a wait-and-see approach, has deferred issuing regulations pending evidence of biotechnology's hazards. Agency Guidelines on Biotechnology, 51 Fed. Reg. 23,347, 23,348 (1986).

the regulatory structure. Finally, inflexibility of regulations could become a problem.²⁷¹ In contrast to the NIH Guidelines, which have evolved as science has advanced, biotechnology regulations issued by the USDA and EPA require formal rulemaking procedures.²⁷²

A challenge to the Coordinated Framework was dismissed in December 1986. The Foundation on Economic Trends challenged the framework on the basis that its scientific base was faulty, it violated NEPA because no EIS was prepared, and it violated the Administrative Procedure Act because its procedural record was inadequate.²⁷³ The District Court for the District of Columbia ruled that the Foundation lacked standing because the framework was not a regulatory rulemaking.²⁷⁴

1. *The National Institutes of Health*

The NIH's role in regulating direct release experiments is drastically curtailed under the 1986 Coordinated Framework. The NIH's policy statement is terse, consisting of an affirmation of the Institutes' support of biomedical research; an intent to continue

OSHA's approach is probably a result of its statutory mandate, under which the agency must show the existence of a significant risk before it can promulgate safety standards. See Occupational Safety and Health Act, 29 U.S.C. § 655(B) (1982); see also *American Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 514 n.32 (1981) (quoting *Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 642 (1980) (OSHA must find "'significant risks' of material health impairment")). See generally Korwek, *OSHA Regulation of Industrial Applications of Recombinant DNA Technology*, 50 U. CIN. L. REV. 284 (1981) (reviewing OSHA's authority to regulate biotechnology).

271. See Recombinant DNA Advisory Committee, Minutes of May 3, 1985 Meeting 16, (statement of R. Mitchell, committee member); see also FIFTEENTH ANNUAL REPORT, *supra* note 95, at 225 (formal updating of risk assessment guidelines is time consuming and expensive; however, scientific basis continues to change rapidly).

272. See, e.g., Coordinated Framework, *supra* note 241, at 23,329 (EPA-proposed rulemaking); *id.* at 23,352 (USDA-proposed rulemaking).

273. See *12 Federal Officials Sued Over Policies: Definitions of Organisms Covered Challenged*, 10 CHEM. REG. REP. (BNA) 504, 504 (July 18, 1986) (citing *Foundation on Economic Trends v. Johnson*, No. 86-1956 (D.D.C. filed July 15, 1986)). The OSTP did not refer to or explain its decision not to prepare an EIS to accompany the Coordinated Framework.

274. See *Foundation Lacks Legal Standing in Suits, Judge Rules in Dismissing Challenges to Policy*, 10 CHEM. REG. REP. (BNA) 1255, 1255 (Jan. 2, 1987).

revision of the NIH Guidelines, the RAC, and ORDA, and revision and oversight of the NIH Guidelines; a summary of the Guidelines; and a statement of proposed deferment, on a case-by-case basis, to the review of certain experiments by other federal agencies.²⁷⁵

The RAC will continue to review direct release experiments at institutions receiving NIH funding, but its policy statement indicates an intent to withdraw from regulation of nonbiomedical research. This situation is unfortunate. The RAC is the most experienced body regulating direct release experiments. To limit review by a body experienced in regulating research, and expand the review authority of an agency such as the EPA, whose expertise lies in regulating products, is troublesome. Although the USDA and the EPA recognize the value of the NIH's experience, the Coordinated Framework does not make a substantial attempt to preserve that experience.²⁷⁶ A RAC working group, formed to comment on the 1984 Coordinated Framework, criticized the proposed multi-agency regulation of biotechnology research.²⁷⁷ One member of the RAC described the 1984 proposal as "an 'enor-

275. Coordinated Framework, *supra* note 241, at 23,349-50. A proposed amendment to the NIH Guidelines suggests omitting the requirement that NIH renew proposals for experiments submitted to other federal agencies. Recombinant DNA Advisory Committee; Meeting, 51 Fed. Reg. 45,650, 45,650-51 (1986).

276. *See, e.g.*, Coordinated Framework, *supra* note 241, at 23,338 (USDA regards NIH Guidelines as model); Rogul, Fowle & Kleffman, *Biotechnology Health Risk Assessment Research Plan*, in RESEARCH NEEDS IN BIOTECHNOLOGY AND THE ENVIRONMENT, FINAL REPORT B-14 (Nov. 1985) (recognizing RAC's extensive risk assessment experience with genetically engineered organisms).

The OSTP stated that other federal agencies have built their policies partially on the NIH Guidelines and experience. Coordinated Framework, *supra* note 241, at 23,305. Several RAC members, however, expressed dismay with the Coordinated Framework. *See, e.g.*, Recombinant DNA Advisory Committee, Minutes of May 3, 1985 Meeting 30 (statement of B. Davis) ("hop[ing] it was crystal clear that a great many people do not think the proposed oversight mechanism is a good one"); *id.* at 29 (statement of B. Talbot, NIH staff member) (suggesting modified RAC in lieu of proposed framework).

277. *E.g.*, Recombinant DNA Advisory Committee, Minutes of May 3, 1985 Meeting 26 (statement of R. Mitchell, committee member) (expressing concern of working group that flexibility of guidelines could be forfeited); *id.* at 27 (statement of R. Clowes, committee member) (expressing working group's opinion that proposed framework was too complicated); *id.* at 28 (statement of D. Friedman, committee member) (expressing working group's impression that proposed framework attempted to reinvent the wheel).

mous can of worms.' ”²⁷⁸

2. *The National Science Foundation*

The NSF is the primary supporter of research into the environmental effects of genetically engineered organisms,²⁷⁹ awarding research grants through its Biotic Systems and Resources Division, promoting interdisciplinary conferences, and advocating research.²⁸⁰ In addition to researching potential environmental effects of biotechnology research, NSF's Scientific Advisory Committee responds to questions arising from NSF-supported and other projects.²⁸¹ The NSF's role appears to be mainly research-oriented. The NSF is responsible for reviewing and approving research funded by itself, but may defer to review or approval by other federal agencies.²⁸²

3. *The United States Department of Agriculture*

The USDA has a longer history of involvement with the introduction of genetically engineered organisms than the other regulatory agencies.²⁸³ USDA has supported the NIH's regulation of biotechnology research funded by the federal government.²⁸⁴ Indeed, the USDA's review of biotechnology research comple-

278. *Id.* at 29 (statement of D. Martin, committee member).

279. H.R. REP. NO. 44, 99th Cong., 1st Sess. 109 (1985).

280. See *Biotechnology Hearing*, *supra* note 235, at 102-03 (statement of D. Kingsbury, Assistant Director, Biological, Behavioral, and Social Sciences Division, NSF).

A \$600,000 study to evaluate the scientific base for potential adverse impacts of direct release experiments was tabled, however, after charges by OSTP that the study was too vague and costly. See *Study of Scientific Base for Regulation of RDNA Products Shelved After Criticism*, 9 CHEM. REG. REP. (BNA) 72, 72 (April 19, 1985); Sun, *Biotech Policy Draws Flood of Comments*, 228 SCIENCE 1296, 1296 (1985).

281. 50 Fed. Reg. at 50,905. The NSF will use its Advisory Committee for Biological, Behavioral and Social Sciences Division, consisting of approximately 10 scientists. Meetings of the committee are open whenever possible. Establishment of Committee, *supra* note 245, at 47,174.

282. See *Coordinated Framework*, *supra* note 241, at 23,306.

283. *Biotechnology Hearing*, *supra* note 235, at 95 (statement of Rep. Sikorski).

284. *Recombinant DNA Research; Actions Under Guidelines*, 48 Fed. Reg. 24,548, 24,549 (1983).

mented the RAC.²⁸⁵ In 1979 the USDA endorsed and adopted the NIH Guidelines, requiring compliance with the Guidelines for all research grantees.²⁸⁶ The USDA's final policy statement, issued in June 1986, contained USDA's proposed Guidelines for biotechnology research at institutions receiving USDA funding, as well as regulations for genetically engineered organisms released into the environment.²⁸⁷

a. The USDA Guidelines

The USDA Guidelines were promulgated under authority of section 1404 of the Food Security Act of 1985.²⁸⁸ The Guidelines closely paralleled the NIH Guidelines, except that they applied to a broader scope of research. Whereas the NIH Guidelines cover only rDNA technology involving two pieces of DNA spliced outside living cells,²⁸⁹ the USDA Guidelines also covered recombinant ribonucleic acid technology, cell fusion, and other forms of agricultural biotechnology.²⁹⁰

The Guidelines were short-lived. In December 1986 the

285. See *Potential Consequences Hearing*, *supra* note 121, at 8 (statement of E. Kendrick, Administrator, Office of Grants and Program Systems, USDA). USDA aids the NIH in all agriculturally related direct release experiments. *Environmental Implications Hearing*, *supra* note 147, at 142 (statement of E. Kendrick). The University of California experiment was reviewed by the USDA Biotechnology Committee. See *Recombinant DNA Research; Actions Under Guidelines*, 48 Fed. Reg. 24,549 (1983).

286. See *Statement of Policy for Regulations, Biotechnology Processes and Products*, 49 Fed. Reg. 50,897, 50,898 (1984) (citing Memorandum to Heads of Department Agencies: Guidelines for Research Involving Recombinant DNA Molecules (Oct. 15, 1979)); see also *Final Policy Statement for Research and Regulation of Biotechnology Processes and Products*, 51 Fed. Reg. 23,336, 23,346 (1986) [hereinafter *Final Policy Statement*] (USDA-sponsored research must comply with NIH Guidelines).

287. See *Advanced Notice of Proposed USDA Guidelines for Biotechnology Research*, 51 Fed. Reg. 23,367, 23,369 (1986) [hereinafter *Advanced Notice of Guidelines*]. A violation of the USDA Guidelines may result in a loss of all USDA funding to the institution. *Id.*

288. Pub. L. No. 99-198, § 1404, 99 Stat. 1354, 1544 (codified at 7 U.S.C. § 3121(12) (Supp. III 1985)). Section 1404 authorizes the Secretary of Agriculture to "establish appropriate controls with respect to the development and use of the application of biotechnology to agriculture." *Id.*

289. See *Recombinant DNA Advisory Committee; Meeting*, 49 Fed. Reg. 696, 697 (1984).

290. *Advanced Notice of Guidelines*, *supra* note 287, at 23,369.

USDA announced its intention to propose a set of revisions to the NIH Guidelines, confirming reports that its original Guidelines had been withdrawn.²⁹¹ It is unclear how much of the procedural structure established by the withdrawn Guidelines will survive. That structure emulated the NIH's structure for regulating biotechnology research. An Agriculture Biotechnology Recombinant DNA Advisory Committee was established to perform functions roughly equivalent to the RAC.²⁹² The Office of Agriculture Biotechnology paralleled ORDA by establishing an administrative center for USDA's biotechnology regulations.²⁹³ Institutional Biosafety Committees similar to NIH's IBCs were designed to operate in research institutions to provide local control over experiments.²⁹⁴ As with approved proposals for direct release experiments issued by the RAC, experiments approved by the USDA Committee would have required EAs.²⁹⁵

USDA proposed the National Biological Impact Assessment Program to provide scientific evaluation of research proposals and to monitor direct release experiments and their effects on the en-

291. *USDA Confirms Dropping Research Rules; January Meeting to Address New Amendments*, 10 CHEM. REG. REP.(BNA) 1195, 1195 (Dec. 15, 1986).

292. Advance Notice of Guidelines, *supra* note 287, at 23,391. The Committee will be composed of 12 members from relevant scientific backgrounds as well as members representing professional conduct, ethics, law, health, and public attitudes. *Id.* Under the withdrawn Guidelines the Committee would have reviewed research proposals and recommended modifications to the Guidelines and protocols. *Id.*

293. *Id.* at 23,390-91. The office was to have assisted the Assistant Secretary for Science and Education in implementing USDA's biotechnology policies and procedures.

294. *Id.* at 23,389-90. Each IBC was to have a minimum of eight members. *Id.* at 23,389. The meetings were to be as open as possible. *Id.*

The Agriculture Biotechnology Recombinant DNA Advisory Committee, the Office of Agriculture Biotechnology, and individual Institutional Biosafety Committees appear to have been established. The USDA submitted a revised flow chart for biotechnology applications to a House subcommittee for inclusion in a report on federal regulation of biotechnology. Although the flow chart was dated October 14, 1986, it was disseminated in January 1987 (after the USDA announced withdrawal of its original Guidelines). See FEDERAL REGULATION OF BIOTECHNOLOGY, *supra* note 257, at 118 (revised).

295. *Advanced Notice of Guidelines*, *supra* note 287, at 23,373. The USDA was to have required a draft EA for each voluntary or required proposal. EAs were to be subsequently prepared by the USDA for approved experiments by using the researchers' drafts. *Id.*

vironment.²⁹⁶ This program has great potential. The USDA has a vast resource base of scientific expertise at its disposal. By calling on its in-house scientific expertise, the Agricultural Research Service, and the land grant system, the USDA should be able to build a substantial data base.²⁹⁷ The broad authority for the proposed USDA Guidelines should permit the revised Guidelines to evolve as available data increases. It is unclear, however, how independent of the NIH Guidelines the revised USDA Guidelines will be.

An important difference between the NIH and the USDA in control of direct release experiments is that the USDA regulations cover both research involving genetically engineered organisms and products developed by biotechnology techniques.²⁹⁸ If research under the USDA Guidelines involves an actual or potential plant pest which is to be released into the environment, the

296. *Id.* at 23,391-92. The data base was to be available for use by the EPA as well as the USDA. *Id.* at 23,318.

The proposed National Biological Impact Assessment Program would formalize previous experiences involving the release of new varieties of animals and plants. The program would include an inventory of favorable test sites for direct release experiments. See Milewski, *Report on Recent Congressional Hearing and Study Conference on Biotechnology*, 9 RECOMBINANT DNA TECHNICAL BULL. 29, 32 (1986). The proposed use of the program has been criticized as "much too cumbersome and diffuse." *Planned Releases Hearing, supra* note 234, at 55 (statement of R. Goodman, Vice President, Research and Development, Calgene). Although the program would provide scientific expertise in evaluating proposed experiments, final decisions were to be made under FPPA by the Animal and Plant Health Inspection Service. See *id.* at 115 (statement of B. Crowley, Senior Associate Director, Resources, Community, and Economic Development Division, U.S. General Accounting Office). The USDA policy statement did not mention what USDA procedure would be followed if the Service made a determination that a genetically engineered organism under review was not a plant pest.

297. See *Potential Consequences Hearing, supra* note 121, at 10 (statement of E. Kendrick, Administrator, Office of Grants and Program Systems, USDA).

298. Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests, 51 Fed. Reg. 23,352, 23,352 (1986). Genetically engineered organisms which would be used as donors, recipients, or vectors, and which are determined to be plant pests are "regulated articles." *Id.* at 23,342-43. The USDA proposed a list of organisms containing plant pests be subject to the regulations. See *id.* at 23,375-77.

The USDA defines "[r]elease into the environment" as the "use of a regulated article outside the constraints of physical confinement that are found in a laboratory, contained greenhouse, or fermenter or other contained structure." See *id.* at 23,342.

scientist conducting the research must comply with the USDA regulations.²⁹⁹ Imposition of the regulations on research subject to the USDA Guidelines complicates the regulatory process. Disputes have arisen between the research branch of the USDA, which administered the Guidelines, and the Animal and Plant Health Inspection Service, which regulates direct release experiments.³⁰⁰ A newly-created Committee on Biotechnology in Agriculture will be the USDA policy mechanism and act as an intermediary between the research guidelines and the regulations.³⁰¹ The Committee will record and refer proposals for direct release experiments, but has no authority to regulate.³⁰²

b. *The USDA Regulations*

USDA's jurisdiction to regulate direct release experiments is based on the Federal Plant Pest Act (FPPA),³⁰³ and the Plant Quarantine Act (PQA).³⁰⁴ The USDA proposes using the FPPA in concert with the PQA to control the movement of genetically engineered plants, plant products, plant pests, or other articles if their movement carries a risk that a plant pest may be intro-

299. *Id.* at 23,355.

300. See Carr, *A Critique of the U.S. Department of Agriculture's Policy on Biotechnology Research and Regulation* 12 (Cong. Research Serv. May 30, 1986) (prepared at the request of Subcomm. on Investigations and Oversight, House Comm. on Science and Technology). Critics of USDA's biotechnology regulatory record believe that regulatory personnel in the Animal and Plant Health Inspection Service have been reluctant to share their regulatory authority with the Science and Education branch of the USDA in certain instances. See *id.* Under the Coordinated Framework, however, the regulatory personnel will be required to base decisions on scientific judgments made by research personnel. See *Planned Releases Hearing, supra* note 234, at 55 (statement of R. Goodman, Vice President, Research and Development, Calgene).

301. See Final Policy Statement, *supra* note 286, at 23,344. The Committee on Biotechnology in Agriculture replaces the Agriculture Recombinant DNA Research Committee. See *Planned Releases Hearing, supra* note 234, at 181 (statement of J. Jordan, Administrator, Cooperative State Research Service, USDA).

302. See *Planned Releases Hearing, supra* note 234, at 181 (statement of J. Jordan, Administrator, Cooperative State Research Service, USDA).

303. 7 U.S.C. §§ 150aa-jj (1982).

304. *Id.* §§ 151-164, 166-167. The USDA also regulates veterinary biologics under the Virus-Serum Toxin Act, 21 U.S.C. §§ 151-158 (1982). Although inoculation of animals with genetically engineered organisms may be classified as a direct release of those organisms, see *infra* note 336, this Article does not discuss this type of experiment.

duced, spread, or established.³⁰⁵ Under the FPPA, the Secretary of Agriculture has jurisdiction over the importation and interstate movement of plant pests.³⁰⁶ The USDA interprets this jurisdictional statement to cover the release into the environment of genetically engineered organisms that are plant pests.³⁰⁷ One commentator questions, however, whether the USDA's jurisdiction reaches direct release experiments involving only the intrastate movement of plant pests.³⁰⁸

The FPPA also provides the Secretary of Agriculture with authority to declare an extraordinary emergency, and "seize, quarantine, treat, [and] apply other remedial measures to destroy or otherwise dispose of exotic plant pests."³⁰⁹ Before remedial action is taken, however, the USDA must determine that a hazard

305. Final Policy Statement, *supra* note 286, at 23,342. The statutory definition of "plant pest" includes:

insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any organisms similar to or allied with any of the foregoing, or any infectious substances, which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, of any processed, manufactured, or other products of plants.

7 U.S.C. § 150aa(c) (1982).

The FPPA is similar in purpose and structure to section 361 of the Public Health and Service Act under which the NIH Guidelines are promulgated. *Cf.* 42 U.S.C. § 264 (1982). *See generally* McGarity, *Legal and Regulatory Issues in Biotechnology*, in *BIOTECHNOLOGY AND THE ENVIRONMENT: RISK AND REGULATION* 137, 149 (1985).

306. 7 U.S.C. § 150bb (1982).

307. Final Policy Statement, *supra* note 286, at 23,342; *see also Planned Releases Hearing*, *supra* note 234, at 177 (statement of J. Wood, Animal and Plant Health Inspection Service, USDA) (movement of genetically engineered organisms from laboratory to field test is within jurisdiction of USDA regulations for interstate and intrastate situations).

308. Carr, *supra* note 300, at 7.

309. 7 U.S.C. § 150dd(a) (1982). The FPPA was enacted to provide the USDA with authority "to protect American agriculture against invasion by foreign plant pests and diseases." H.R. REP. No. 289, 85th Cong., 1st Sess. 2 (1957). In the proposed rule for biotechnology, the USDA reads "foreign" to mean exotic. *See* Final Policy Statement, *supra* note 286, at 23,353. The USDA explains that the release of regulated articles into the environment "is tantamount to the introduction of an organism which is 'new to and not theretofore known to be widely prevalent or distributed with and throughout the United States' and which there is reason to believe is a plant pest." *Id.* (quoting 7 U.S.C. § 150dd(a) (1982) (emergency disposal powers of Secretary of Agriculture)).

actually exists.³¹⁰ The USDA proposed new regulations under the FPPA and PQA to require permits or certificates of exemption for the introduction of genetically engineered organisms that are potential or actual plant pests.³¹¹ Applications for permits, which may be issued conditionally,³¹² must be submitted a minimum of 180 days prior to a proposed direct release experiment.³¹³ The 180-day time period, which has been criticized by industry as too lengthy,³¹⁴ could lead to forum shopping by scientists to come under the shorter periods proposed by the EPA.³¹⁵

310. See *Planned Releases Hearing*, *supra* note 234, at 177-78 (statement of J. Wood, Animal and Plant Health Inspection Service, USDA).

311. Final Policy Statement, *supra* note 286, at 23,361 (to be codified at 7 C.F.R. § 340.0). Potential or actual plant pests are referred to by the USDA as regulated articles. *Id.* (to be codified at 7 C.F.R. § 340.1). The proposed regulations list certain organisms considered to be plant pests. *Id.* at 23,362-63 (to be codified at 7 C.F.R. § 340.2). The USDA stated that the FPPA was enacted to be gap-filling legislation to protect American agriculture from exotic plant pests and diseases. The agency includes genetically engineered organisms within the Act's scope. See *id.* at 23,353.

The USDA mentioned the Federal Noxious Weed Act, 7 U.S.C. §§ 2801-2812 (1982), as an additional statute under which to regulate genetically engineered organisms. Final Policy Statement, *supra* note 286, at 23,353. The Act is similar to the FPPA in requiring a permit, 7 U.S.C. § 2803(a) (1982), applying to releases into the environment, *id.* § 2805, and providing the Secretary with power to eradicate and suppress the movement of noxious weeds in the environment. *Id.* § 2808. A House subcommittee stated that the Federal Noxious Weed Act "may provide USDA with its broadest authority to regulate deliberate releases." ENVIRONMENTAL IMPLICATIONS REPORT, *supra* note 203, at 37. *But see* Carr, *supra* note 300, at 7 (Federal Noxious Weed Act's requirement that organisms may not be regulated until: (1) their identification as noxious weeds in regulations issued after notice and hearing; and (2) a determination by the Secretary of Agriculture that the noxious weeds will probably be harmful, are serious disadvantages to using the Act to regulate genetically engineered organisms.); Korwek & de la Cruz, *Federal Regulation of Environmental Releases of Genetically Manipulated Microorganisms*, 11 RUTGERS COMPUTER & TECHNICAL L. REV. 301, 349-54 (1958) (discussing applicability of Federal Noxious Weed Act to regulation of direct releases).

312. 51 Fed. Reg. at 23,364 (to be codified at 7 C.F.R. § 340.3(c)). Conditions may include remedial measures, reporting results, and monitoring by the Department of Agriculture. *Id.* Violation of conditions may result in withdrawal of the permit. *Id.* at 23,365 (to be codified at 7 C.F.R. § 340.3(d)).

313. *Id.* at 23,364 (to be codified at 7 C.F.R. § 340.3(a)). Certificates of exemption may be issued on application. *Id.* at 23,364 (to be codified at 7 C.F.R. § 340.4)).

314. See 'Fine Tuning' Recommended by Industry for USDA Proposed Rules on Plant Pests, 10 CHEM. REG. REP. (BNA) 574, 574 (Aug. 1, 1986).

315. See 51 Fed. Reg. at 23,321-22 (proposing 30-90 day review under FIFRA); *id.* at 23,326 (proposing 90 day review under TSCA). The EPA and

Commentators have questioned whether the FPPA's language covers pests that pose only a risk of harm to plants.³¹⁶ The Act applies when pests "can" harm plants.³¹⁷ USDA's determination that genetically engineered plants containing *Rhizobium* bacteria are harmful implies that the agency may intend to read the provision broadly. The agency stated in December 1984 that certain strains of the nitrogen-fixing bacteria caused leaf yellowing.³¹⁸ The 1986 proposed regulations, however, cover the entire genus *Rhizobium*.³¹⁹ The USDA has also listed *Pseudomonas* bacteria as a genus to be regulated.³²⁰ The ice-nucleating negative bacteria to be used in the University of California experiment is a strain of this genus. The remedial nature of the FPPA, however, could preclude regulation of genetically engineered organisms for which no harmful effects on plants have been identified,³²¹ even if qualities harmful to human health and the environment have been identified.

An additional disadvantage of the FPPA is the risk-benefit

USDA procedures also differ in comment periods. The USDA, unlike the EPA, does not require comment periods. See FEDERAL REGULATION OF BIOTECHNOLOGY, *supra* note 257, at 88.

316. See generally McChesney & Adler, *Biotechnology Released from the Lab: The Environmental Regulatory Framework*, 13 ENVTL. L. REP. (Envtl. L. Inst.) 10,366, 10,376 (1983).

317. See 7 U.S.C. § 150aa(c) (1982).

318. 49 Fed. Reg. at 50,902.

319. 51 Fed. Reg. at 23,362 (to be codified at 7 C.F.R. § 340.2). Cf. Brill, *Safety Concerns Regarding Genetically Engineered Plants and Microorganisms to Benefit Agriculture*, reprinted in *Potential Consequences Hearings*, *supra* note 121, at 77 (exotic strains of *Rhizobium* are already used worldwide in large numbers as nitrogen fixants).

320. 51 Fed. Reg. at 23,362 (to be codified at 7 C.F.R. § 340.2). The USDA stated, however, that an applicant could submit data to indicate that the strain of *Pseudomonas syringae* being tested was not pathogenic and was therefore not a plant pest. *Id.* at 23,347.

In the University of California experiment, only strains of *Pseudomonas syringae* that were not pathogenic to area crops were introduced. ENVIRONMENTAL ASSESSMENT, *supra* note 176, at 25. If pathogenic strains of the ice-nucleating negative bacteria are to be tested, the USDA intends to regulate them even though the genetically engineered strains would be no more pathogenic than their natural counterparts. See *id.*

321. See Carr, *supra* note 300, at 8; see, e.g., *Biotechnology Development Hearings*, *supra* note 259, at 148 (statement of Rep. Wyden) (private firm requested review of herbicide-resistant tobacco plants and USDA returned application because plants were not plant pests or plant pathogens).

analysis requirement,³²² which would mean weighing speculative risks against speculative benefits. In addition, the USDA may be inadequately staffed to review complex applications for the release and movement of genetically engineered organisms defined as plant pests. In 1985 the agency processed over six thousand applications to move plant pests.³²³

Prior to publication of the 1986 policy statement and proposed rule, USDA's biotechnology policy was severely criticized. The public, and subsequently Congress, challenged the agency's allegedly inadequate review and approval for commercial sale of a genetically engineered live virus.³²⁴ On a second front, a General Accounting Office study strongly criticized USDA's regulatory system for biotechnology. The study considered USDA's policy statement to be vague,³²⁵ its regulatory procedures to be poorly coordinated and confusing,³²⁶ particularly those concerning direct release experiments,³²⁷ and the agency's emphasis on biotechnology's benefits as displaying a lack of sensitivity to potential risks.³²⁸ The study noted that USDA was attempting to remedy the situation,³²⁹ but emphasized that continuing battles with the EPA over regulation were a cause for concern.³³⁰ Even under the

322. 7 C.F.R. § 330.204 (1986).

323. See 'Fine Tuning' Recommended by Industry for USDA Proposed Rules on Plant Pests, 10 CHEM. REG. REP. (BNA) 574, 574 (Aug. 1, 1986).

324. See Sun, *USDA Biotechnology Review Criticized and Defended*, 232 SCIENCE 316, 316 (1986); see also *USDA Licensing of a Genetically Altered Veterinary Vaccine, Subcomm. on Department Operations, Research, and Foreign Agriculture of the House Comm. on Agriculture, and the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 99th Cong., 2d Sess. (1986).

325. AGRICULTURE'S REGULATORY SYSTEM, *supra* note 253, at 57.

326. *Id.* at 42-43.

327. *Id.* at 34.

328. *Id.* at 60.

329. *Id.* at 44.

330. *Id.* at 47. See also *White House Plan Calls for Joint Reviews When EPA, Agriculture Jurisdictions Overlap*, 10 CHEM. REG. REP. (BNA) 59, 59 (Apr. 18, 1986) (referring to turf disputes between USDA and EPA as reason for delay of biotechnology regulations). The jurisdictional argument between USDA and EPA is not new. In 1970, EPA succeeded the USDA as the agency responsible for administering pesticide regulations. See Ebner, *EPA's New Pesticide Review Rules*, 4 ENVTL. F. 40, 40 (July 1985). The USDA, however, continues to be active in researching pesticides prior to the time they are ready to be marketed. See *Potential Consequences Hearing*, *supra* note 121, at 14 (statement of E. Kendrick, Administrator, Office of Grants and Program Systems, USDA).

significantly broader jurisdiction over biotechnology asserted by the 1986 statement, the USDA will still be open to criticism, however, for promoting and regulating biotechnology concurrently.³³¹ The USDA could also be placed in a dilemma if called upon to regulate genetically engineered organisms that promoted agricultural production while concurrently harming the environment.³³²

4. *The Environmental Protection Agency*

EPA's concern about the environmental impacts of biotechnology began in the mid-1970s. The EPA has been particularly concerned about the lack of discussion of environmental implications of experimentation in the NIH Guidelines.³³³ Whereas the USDA's approach to biotechnology was not to regard genetically engineered products as unique, and initially to defer scientific experiments to the NIH, the EPA was more assertive, causing the agency to be cast in the role of "chief Philistine."³³⁴

Unlike USDA, the EPA initially treated regulation of genetically engineered organisms differently from regulation of organisms created by conventional means.³³⁵ EPA abandoned this concept in 1986 and replaced it with review of microorganisms released in the environment, which are either pathogenic (or include genetic material derived from pathogens), or which include new traits or characteristics.³³⁶ As a general rule, intergeneric or

Jurisdictional disputes are not limited to the USDA and the EPA. *See, e.g., Wehr, Congress to Consider Impact, Problems of Gene Engineering*, 42 CONG. Q. 3093, 3095 (1984) (describing 18-month long dispute between USDA and FDA over regulation of genetically engineered bovine growth hormone).

331. *See Potential Consequences Hearings, supra* note 121, at 11 (discussion between E. Kendrick, Administrator, Office of Grants and Program Systems, USDA, and Sen. D. Durenberger); *see also Planned Releases Hearing, supra* note 234, at 76-77 (statement of R. Colwell, Professor, Department of Zoology, University of California, Berkeley) (questioning objectivity of USDA in regulating USDA-funded biotechnology research).

332. *See Carr, supra* note 300, at 8 (questioning whether USDA is legally able to protect environmental interests that harm agriculture).

333. Minutes of Public Meeting of the EPA Administrator's Toxic Substances Advisory Committee 9 (Nov. 16, 1982).

334. *Advisory Role, supra* note 175, at 5.

335. Proposed Policy Concerning Certain Microbial Products, 49 Fed. Reg. 50,880, 50,884-85 (1984) (codified at 40 C.F.R. §§ 150-189 (1986)) (proposed Dec. 31, 1984) [hereinafter Proposed Policy].

336. Statement of Policy; Microbial Products Subject to the Federal Insecti-

pathogenic genetically engineered organisms are subject to regulation, but intrageneric or nonpathogenic genetically engineered organisms are not.³³⁷ The technique by which the organisms are genetically engineered is no longer the criterion triggering regulation.³³⁸

EPA jurisdiction to regulate biotechnology rests on two statutes, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),³³⁹ and the Toxic Substances Control Act (TSCA).³⁴⁰

cide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, 51 Fed. Reg. 23,313, 23,315 (1986) [hereinafter Statement of Policy]. Because of the difficulty in defining "environmental release," the EPA focused on defining "containment." See *id.* at 23,316, 23,335. Before publication of the 1986 Coordinated Framework, a biotechnology firm contended that a tree growing on the firm's rooftop constituted a contained facility. See *Releasing Genetically Engineered Organisms Into the Environment: Hearing Before the Subcomm. on Toxic Substances and Environmental Oversight of the Senate Comm. on Environment and Public Works*, 99th Cong., 2d Sess. 52 (1986) [hereinafter *Releasing Genetically Engineered Organisms Hearing*] (statement of Sen. Volkmer). In addition, a Texas university scientist argued that innoculating pigs with a genetically engineered vaccine did not constitute an environmental release. *Id.* at 54.

A new trait or characteristic may be in the novel organism or in the environment into which the novel organism is released. Statement of Policy, *supra*, at 23,317. The EPA focuses its regulations on microorganisms containing genetic material from dissimilar sources because of a determination that these microorganisms are more likely to develop new, and therefore unpredictable, combinations of traits. *Id.* This analysis has been criticized, however. See *Federal Policy Could Miss Full Review of Some Harmful Products, Scientists Say*, 10 CHEM. REG. REP. (BNA) 516, 516 (July 25, 1986).

337. Statement of Policy, *supra* note 336, at 23,317. The EPA defines intergeneric combinations, but not intrageneric combinations, as dissimilar. *Id.* Certain intergeneric combinations are exempt if they contain predictable quantitative traits. *Id.*

338. See *id.* at 23,330 (defining genetic engineering as "[a]ny human intervention beyond removal from the environment and selection for the desired variant populations").

The OMB criticized the EPA for considering in the 1984 proposed framework whether to include organisms produced by "transformation, transduction, transfection, and techniques that promote conjugation and plasmid transfer" in addition to organisms produced by recombinant ribonucleic acid and cell fusion. Proposed Policy, *supra* note 335, at 50,887-88. See Sun, *Regulatory Structure for Biotechnology Proposed*, 227 SCIENCE 274, 274 (1985). The 1986 Coordinated Framework continues the broad definition of biotechnology, 51 Fed. Reg. at 23,302, but focuses on the nature of the genetically engineered organism, for example, its derivation from pathogenic or intergeneric organisms. *Id.* at 23,306-07.

339. 7 U.S.C. §§ 136-136y (1982).

340. 15 U.S.C. §§ 2601-2629 (1982).

a. *The Federal Insecticide, Fungicide and Rodenticide Act*

EPA regulations under FIFRA require permits for experiments conducted to gather information on pesticides not registered with the EPA.³⁴¹ An exemption to this requirement is available if experiments are conducted to evaluate organisms for pesticide purposes or to determine their properties, for example, toxicity.³⁴² To come within this exemption, experiments must be conducted on less than ten acres of land, and all food crops must be destroyed or consumed by experimental animals.³⁴³

In 1984, EPA modified the procedures for obtaining experimental use permits (EUPs) for direct release experiments involving genetically engineered organisms.³⁴⁴ EPA's rationale was that because genetically engineered organisms possessed the potential to replicate and spread beyond the experiment site, small scale experiments with these organisms were equivalent to large scale experiments with conventionally produced organisms.³⁴⁵ The 1986 policy statement further modified EPA's procedures by creating two levels of review.

Level I reporting provides a thirty-day review procedure for intragenetic or nonpathogenic genetically engineered organisms.³⁴⁶ If a researcher does not receive a negative response within the thirty-day period, the direct release experiment may proceed.³⁴⁷ However, if the EPA determines that the proposed ex-

341. 40 C.F.R. § 172.2(a) (1986).

342. *Id.* § 172.3(a) (1986). An additional requirement is that the experiment must not be conducted in order to obtain benefits from pest control. *Id.*

343. *Id.* § 172.3(a)(1) (1986). An exemption from the requirement that crops be destroyed is available if tolerance levels for the pesticide have been established. *Id.*

344. See *Biotechnology Hearing, supra* note 235, at 90 (statement of J. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA). EPA first proposed regulations for microbial pesticides in 1979. See Regulation of "Bio-organismal" Pesticides; Policy Statement and Notice of Availability of Background Document, 44 Fed. Reg. 28,093 (1979); see also 40 C.F.R. § 158.65(b)(2) (1986).

345. Microbial Pesticides; Interim Policy on Small Scale Field Testing, 49 Fed. Reg. 40,659, 40,660 (1984); see also Statement of Policy, *supra* note 336, at 23,330 (excluding certain direct release experiments from small-scale exemption of TSCA because of genetically engineered organisms' potential for reproduction).

346. Statement of Policy, *supra* note 336, at 23,321.

347. *Id.* In August 1986, the EPA approved a Montana State University experiment involving the planting of grain kernels onto which a genetically engineered fungus had been applied to act as a herbicide against two weed species.

periment should be monitored, or that additional information is required, the applicant is notified, and may then apply for an EUP under FIFRA,³⁴⁸ or Level II notification.

Level II notification, which is used for intergeneric or pathogenic genetically engineered organisms, requires a more detailed application than Level I reporting. The EPA has ninety days from submission of supporting data to determine whether the proposed experiment should proceed.³⁴⁹ During the ninety-day period, the EPA reviews the proposal and assesses potential risks in consultation with other federal agencies and relevant authorities of the state where the experiment is to be located. The EPA then writes a scientific evaluation of the proposed experiment.³⁵⁰ If a proposed experiment involves controversial or complex scientific questions, it is independently reviewed by EPA's Biotechnology Science Advisory Committee.³⁵¹

After review of an experiment, the EPA issues a determination stating whether the experiment may proceed or whether the researcher must apply for an EUP. An EUP may be required if additional risk assessment data is needed, if modification or limitation of the experiment is deemed necessary, or if the EPA determines that test data needs to be developed.³⁵² Proposals for an EUP are published in the *Federal Register* and reviewed by the

The EPA's risk assessment was supported by its Scientific Advisory Panel, the NIH, the USDA, the NSF, and the FDA. Because the risk was found to be minimal, no EUP was required. *See Field Testing Approved for Fungus: EPA Requires No Experimental Use Permit*, 10 CHEM. REG. REP. (BNA) 607, 607 (Aug. 8, 1986).

348. Statement of Policy, *supra* note 336, at 23,321; *see* 40 C.F.R. § 172.4 (1986).

349. Statement of Policy, *supra* note 336, at 23,322.

350. *Id.*

351. *Id.* at 23,323. Until the Biotechnology Science Advisory Committee was established, the EPA's Scientific Advisory Panel reviewed proposed experiments. *Id.*

The EPA's Biotechnology Science Advisory Committee reviews complex Level II applications. *Id.* *See also id.* at 23,318-19 (discussing proposed committee); Establishment of the Biotechnology Science Advisory Committee, *id.* at 24,221-22 (committee charter). The Committee advises the EPA pursuant to FIFRA, TSCA, and other relevant statutes. *Id.* at 24,221. *See also* Environmental Protection Agency, Biotechnology Science Advisory Committee; Request for Suggestions for List of Candidates, *id.* at 24,220 (requesting suggestions for committee members from specified scientific disciplines).

352. 51 Fed. Reg. at 23,323.

EPA within 120 days of submission.³⁵³

The extension of EPA review under FIFRA to research has caused anxiety in industrial circles. Traditionally, EPA has only disclosed limited data on pesticides prior to an application for registration or an EUP.³⁵⁴ Before the registration or EUP is applied for, industry may be unwilling even to admit that a microbial pesticide is ready for testing because of the potential for economic damage that may be caused by disclosure to competitors.³⁵⁵

EPA determined that the bacteria involved in the University of California experiment was subject to FIFRA.³⁵⁶ The EPA defined the genetically engineered bacteria as a pesticide due to its capacity to replace the natural bacteria that has the capacity for ice nucleation. Under this analysis, the natural bacteria are pests.³⁵⁷ The experiment finally received federal and state approval in 1986, but subsequently encountered local opposition.³⁵⁸

353. *Id.* See 40 C.F.R. §§ 172.4-.8 (1986). Denial of an EUP may be appealed to the EPA Administrator. 40 C.F.R. § 172.10 (1986).

354. See Withers, *supra* note 129, at 678. Disclosure of confidential data and trade secrets is only permitted for applications for EUPs or registration under FIFRA if the EPA Administrator determines that "an unreasonable risk of injury to health or the environment" exists. 7 U.S.C. § 136h(d)(1) (1982). The disclosure is subject to stringent procedures. See *id.* § 136h(d)(3) (1982); see also Abramson, *Confidential Business Information Versus the Public's Right to Disclosure—Biotechnology Renews the Challenge*, 34 U. KAN. L. REV. 681, 686 (1986) (describing EPA procedure). TSCA also contains confidential data protection provisions. See 15 U.S.C. § 2613 (1982).

355. See Withers, *supra* note 129, at 678; see also Abramson, *supra* note 354, at 699-700 (suggesting changes to FIFRA to limit preregistration disclosure of confidential data).

356. See Abramson, *supra* note 354, at 693. An additional problem for applicants for Level I and Level II review may be caused by the Coordinated Framework's ambiguous data requirements which could lead to delays in approving applications. See FEDERAL REGULATION OF BIOTECHNOLOGY, *supra* note 257, at 94.

357. See *Insuring Safety in Genetic Engineering*, 10 EPA J. 32, 32 (June 1984). But see *Biotechnology and Agriculture Hearings*, *supra* note 238, at 318 (statement of George H. Kidd, L. William Tewles & Co.) ("[I]ce-nucleating bacteria [is] not considered a pesticide, but it is considered a crop protection chemical [s]o if you consider [FIFRA] to cover crop protection chemicals and not just pesticides, then your ice-nucleating bacteria fits very nicely.").

358. See Sun, *Field Test of Altered Microbe Still in Limbo . . .*, 232 SCIENCE 1340, 1340 (1986). EPA required the University of California scientists to furnish additional information to that required by the NIH. See Sun, *supra* note 280, at 1296.

A proposed direct release experiment by Monsanto in Missouri also encoun-

In August 1986, a California court postponed the experiment after finding that the EPA and the California Department of Food and Agriculture failed to evaluate the experiment's potential effects on the environment in compliance with the California Environmental Quality Act.³⁵⁹ Under the terms of a negotiated settlement, the University of California is amending its environmental assessment to reflect residents' concerns.³⁶⁰

Meanwhile, Jeremy Rifkin filed suit to prevent a similar experiment by Advanced Genetic Sciences.³⁶¹ The firm proposed applying ice nucleation negative bacteria to strawberry plants to test the bacteria's frost preventive capabilities. Because of concerns regarding the novel bacteria's capacity to disperse, colonize, and potentially affect precipitation patterns, the EPA—with the advice of a subpanel of its scientific advisory panel—had requested an EUP.³⁶² On the day that the EPA issued the EUP, Rifkin filed suit, charging that the EPA's decision violated NEPA and FIFRA and was arbitrary and capricious under the Administrative Procedure Act.³⁶³ In denying a preliminary injunction to halt the experiment, the federal District Court for the District of Columbia ruled that the EPA's procedures complied with

tered local opposition. The location of the direct release experiment (on Monsanto's land in a floodplain) made the experiment subject to county zoning laws. See *EPA Decision on Monsanto Microbe Permit Deferred Pending Further Study by Company*, 10 CHEM. REG. REP. (BNA) 228, 228 (May 23, 1986).

359. *Californians for Responsible Toxics Mgt. v. Regents of Univ. of Cal.*, No. 342,097 (temporary injunction granted Aug. 1, 1986) (cited in *California Judge Postpones Planned Test of Genetically Altered Bacteria on Potatoes*, 10 CHEM. REG. REP. (BNA) 601, 601 (Aug. 8, 1986)); see CAL. PUB. RES. CODE § 21061 (West 1977). The plaintiffs attacked the experiment on procedural grounds and on the basis that the researchers should be required to present evidence supporting their claim that the experiment did not pose risks. See *California Judge Postpones Planned Test of Genetically Altered Bacteria on Potatoes*, 10 CHEM. REG. REP. (BNA) 601, 601 (Aug. 8, 1986).

360. See Crawford, *Lindow Microbe Test Delayed by Legal Action Until Spring*, 233 SCIENCE 1034, 1034 (1986).

361. *Foundation on Economic Trends v. Thomas*, 637 F. Supp. 25 (D.D.C. 1986).

362. *Id.* at 26-27. The EPA had contacted the scientists upon whose research Jeremy Rifkin based his argument that rainfall patterns could be disrupted by the experiment. See *id.* at 27; See also Sun, *supra* note 192, at 1015. The subpanel reviewing the application included a soil microbiologist, a plant pathologist, a microbiologist-toxicologist, a microbial ecologist, a meteorologist, and a community ecologist. See *Id.*

363. 637 F. Supp. at 25, 27.

FIFRA,³⁶⁴ and were the functional equivalent of NEPA's procedural mandate.³⁶⁵ Applying the deferential scientific review standard, the court found that the EUP was substantively adequate.³⁶⁶

As the court noted, however, the experiment was delayed until a local restriction was lifted³⁶⁷ and until the EPA investigated charges that Advanced Genetic Sciences illegally injected genetically engineered organisms into trees growing on the firm's roof in Oakland, California. The EPA subsequently suspended the EUP during its investigation of the violation and fined Advanced Genetic Sciences for the violation.³⁶⁸ In 1987 EPA reissued the per-

364. *Id.* at 28-29.

365. *Id.* (citing *Environmental Defense Fund, Inc. v. EPA*, 489 F.2d 1247, 1256 (D.C. Cir. 1973)). EPA is generally exempt from NEPA for its regulatory actions. *Wyoming v. Hathaway*, 525 F.2d 66, 71-72 (10th Cir. 1975), *cert. denied*, 426 U.S. 906 (1976); *see also* *Warren County v. North Carolina*, 528 F. Supp. 276, 286 (E.D.N.C. 1981) (listing cases holding that EPA is not required to file EIS); *Biotechnology Hearing, supra* note 235, at 89 (statement of Rep. Dingell) (EPA is specifically exempt from NEPA.); *CEQ Hearing, supra* note 230, at 17 (statement of A. Hirsch, Director of Office of Federal Activities, EPA) (While EPA voluntarily complies with NEPA, the EPA's NEPA responsibilities are limited to construction grants, research and development programs, facility support activities, and new source National Pollutant Discharge Elimination System permits.). For a discussion of EPA's scientific review of the application, *see* *Abramson, supra* note 354, at 695-96.

366. 637 F. Supp. at 28 (citing *Baltimore Gas & Electric Co. v. Natural Resources Defense Council, Inc.*, 462 U.S. 87, 103. The firm's proposal was reviewed by the NIH, the USDA, and the FDA. *Id.* at 27.

367. *Id.* at 29. The Monterey County ordinance required the firm to obtain a land use permit to conduct the experiment. Authority for the ordinance was based on the danger to public health posed by the use of "animals" (i.e., bacteria) in the experiment. *See Ice-Minus Field Test in California Put on Hold After Monterey County Hearing*, 9 CHEM. REG. REP. (BNA) 1458, 1458 (Jan. 31, 1986).

Because the strawberry experiment was to be carried out in California, state permission also was required. Permission was granted effective January 15, 1986. *See California Gives Okay to Field Test of Ice-Minus Bacteria; Lawsuit Pending*, 9 CHEM. REG. REP. (BNA) 1302, 1302 (Jan. 3, 1986).

Professor Emerson has raised the question of whether state and local regulations that suppress scientific information are constitutional because they are not the least drastic means available to regulate scientific research. *SCIENCE POLICY REPORT, supra* note 16, at 60 (statement of T. Emerson, Professor, Yale School of Law). The constitutional issue was not raised in this case.

368. 637 F. Supp. at 29. Advanced Genetic Sciences was originally fined \$20,000 for violating its EPA permit and for knowingly falsifying data on the permit application. After negotiations with the EPA, the charge of knowingly falsifying experimental data was dropped and the fine reduced to \$13,000. *See* *Sun, EPA*

mit; the experiment is expected to be conducted within the year.³⁶⁹

A major disadvantage to regulating genetically engineered organisms under FIFRA is that the Act was not written to apply to genetically engineered organisms. This raises the question of whether the organisms are covered by the statute.³⁷⁰ Commentators suggest that FIFRA's applicability to genetically engineered organisms could be limited by virtue of the statute's definition of a "pesticide" to mean a "substance."³⁷¹ Commentators expect courts to defer to EPA's broader interpretation, however, because it is consistent with Congress' intent to broadly define the term "pesticide."³⁷²

b. The Toxic Substance Control Act

TSCA has been described as the most comprehensive statute under which biotechnology could be regulated.³⁷³ The EPA has

Reduces Penalty Against Biotech Firm, 232 SCIENCE 1495, 1495 (1986).

369. See Crawford, *EPA Okays Field Test*, 235 SCIENCE 840, 840 (1987). The proposed site for the experiment was the residential backyard of an official of Advanced Genetic Sciences in Monterey County. The county refused permission for the experiment under its zoning authority. See *Releasing Genetically Engineered Organisms Hearing*, *supra* note 336, at 52 (statement of Sen. Volkmer). The EPA reissued the permit after approving more rural locations for the experiment. See Crawford *supra*, at 840. The firm will have to comply with the California Environmental Quality Act before proceeding with the experiment. See *supra* notes 359-60 and accompanying text.

370. See *Biotechnology Hearing*, *supra* note 235, at 83 (statement of Rep. Sikorski).

371. McChesney & Adler, *supra* note 316, at 10,374-75; see 7 U.S.C. § 136u (1982) (defining pesticide as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest [or] intended for use as a plant regulator, defoliant or desiccant").

372. McChesney & Adler, *supra* note 316, at 10,375. EPA has considered that living organisms can be pesticides since 1979, when the agency determined that "[t]he language of FIFRA gives the Agency a very broad regulatory authority. As applied to biological pesticides, the definition includes, the many diverse microscopic life forms which can be and are utilized in programs of biological control . . ." Environmental Protection Agency, Regulation of "Biorational" Pesticides; Policy Statement and Notice of Availability of Background Document, 44 Fed. Reg. 28,093, 28,094 (1979). EPA has deferred to USDA for regulation of most biological control agents. See *Certain Biological Control Agents; Proposed Exemption from Regulation*, 46 Fed. Reg. 18,322, 18,323 (1981).

373. McGarity, *supra* note 305, at 149.

authority under TSCA to regulate chemical substances.³⁷⁴ A "chemical substance" is statutorily defined as "any organic or inorganic substance of a particular molecular identity, including . . . any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature" ³⁷⁵ EPA has determined that this definition covers genetically engineered organisms.³⁷⁶

EPA bases its interpretation on three factors: (1) TSCA's legislative history indicates Congress' intent that "chemical substance" be broadly interpreted;³⁷⁷ (2) TSCA's language includes "naturally occurring substances" under the definition of chemical substances;³⁷⁸ and (3) Congress' intent that TSCA applies to substances not covered under other environmental and health laws.³⁷⁹ Commentators disagree as to whether the EPA's interpretation is correct.³⁸⁰ Certainly the authors of TSCA—like the au-

374. 15 U.S.C. § 2603 (1982).

375. *Id.* § 2602(2)(A) (1982).

376. Statement of Policy, *supra* note 336, at 23,324. In its 1984 proposed policy statement, the EPA stated that genetically engineered organisms were covered by TSCA because "any DNA molecule, other nucleic acid, or other constituent of a cell, however created, is an 'organic substance of a particular identity.'" Proposed Policy, *supra* note 335, at 50,886; *see also* McGarity & Bayer, *supra* note 81, at 506 ("DNA molecule within a genetically engineered microorganism would seem to fit the statutory definition of chemical substance"). *But see* EPA ADMINISTRATOR'S TOXIC SUBSTANCES ADVISORY COMMITTEE, ENVIRONMENTAL PROTECTION AGENCY, ATSAOBS OBSERVATIONS AND RECOMMENDATIONS ON BIOTECHNOLOGY (June 28, 1983) ("case for TSCA applying to the intentional release of genetically-engineered living organisms is less clear [than for release of biotechnology products]").

377. *See* Proposed Policy, *supra* note 335, at 50,887. *But see Environmental Implications Hearing, supra* note 147, at 224 (letter from G. Karny, answering committee question) ("no one knows complete chemical make-up of any living organism").

378. Proposed Policy, *supra* note 335, at 50,887 (quoting 15 U.S.C. § 2602(2)(A) (1982)). *But see Environmental Implications Hearing, supra* note 147, at 224 (letter from G. Karny, answering committee question) ("definition of chemical substance does refer to substances occurring in nature, but I would not read that as the key part of the definition").

379. *See Proposed Policy, supra* note 335, at 50,887.

380. *Compare Environmental Implications Hearing, supra* note 147, at 224 (letter from G. Karny, answering committee question) ("consensus has developed among the experts that TSCA probably covers genetically modified organisms," but expressing personal reservations on issue) *with* ENVIRONMENTAL IMPLICATIONS REPORT, *supra* note 203, at 33 (noting argument that "no indication whatsoever exists that Congress intended TSCA to cover genetically engineered life forms") and Schiffbauer, *Regulating Genetically Engineered Microbial Products Under*

thors of FIFRA—did not intend the Act to apply to genetically engineered organisms,³⁸¹ but this does not necessarily foreclose TSCA's application to the organisms.³⁸²

The EPA's determination that TSCA covers genetically engineered organisms³⁸³ means that all genetically engineered organisms are subject to regulation under TSCA unless specifically exempted. Exemptions, based on use, include food, pesticides, drugs, and cosmetics, which are covered by other statutes.³⁸⁴

the Toxic Substances Control Act, 15 ENVTL. L. REP. (Envtl. L. Inst.) 10,279, 10,281 (1985) (“[C]lose examination of the Senate and House reports and floor debate surrounding passage of TSCA is inconclusive as to whether or not Congress intended ‘chemical substances’ to be interpreted so broadly as to include genetically engineered microbial products.”) and Wehr, *supra* note 330, at 3097 (quoting member of genetic engineering firm as stating that if TSCA defines living organism as chemical substances, “‘EPA could regulate the President under TSCA’”).

In 1984, the staff of the Subcommittee on Investigations and Oversight of the House Committee on Science and Technology recommended that EPA use TSCA to regulate direct releases of genetically engineered organisms. The subcommittee stated that because EPA had concluded that TSCA provided sufficient authority, new legislation was unnecessary at that time. The subcommittee did not endorse EPA's actions under TSCA, but expressed reservations about EPA's ability to regulate under TSCA in light of its poor performance in the past. ENVIRONMENTAL IMPLICATIONS REPORT, *supra* note 203, at 50; *see also* GENERAL ACCOUNTING OFFICE, ASSESSMENT OF NEW CHEMICAL REGULATION UNDER THE TOXIC SUBSTANCES CONTROL ACT 29-30 (1984) (criticizing EPA's implementation of research and development exemption of TSCA).

381. *See Biotechnology Hearing, supra* note 235, at 83 (statement of Rep. Sikorski).

382. *Cf. United States v. Chakrabarty*, 447 U.S. 303, 316 (1980). In determining whether the Patent Act, 35 U.S.C. § 101 (1982), covered genetically engineered organisms when the existence of such organisms was not foreseeable when the Act was passed, the Court found the broad language of the Act applicable. 447 U.S. at 316. An analogy can be made between the Patent Act and TSCA. Whereas the Patent Act was designed to apply to inventions that were not foreseeable when the Act was passed, TSCA was designed to apply to chemical substances that did not exist when that Act was passed.

In 1977, the EPA extended TSCA coverage to yeast, bacteria, and fungi, by stating that the “definition [chemical substances] does not exclude life forms which may be manufactured for commercial purposes and nothing in the legislative history would suggest otherwise.” Regulations Under the Toxic Substances Control Act, 42 Fed. Reg. 64,572, 64,584-85 (1977).

383. Statement of Policy, *supra* note 336, at 23,324. Among the genetically engineered organisms that the EPA proposes to regulate under TSCA are those used for nitrogen fixation of plants, metal extraction, pollutant degradation, and enhanced oil recovery. *Id.*

384. *See* 15 U.S.C. § 2602(2)(B) (1982).

Plants and animals are also generally exempt from TSCA.³⁸⁵

EPA's determination that genetically engineered organisms are subject to TSCA does not mean that all direct release experiments are covered by the statute. EPA proposes regulating only commercial research, which is broadly defined to include research conducted under industry-university contracts where the company holds patent rights or trade secrets, or research for "the purpose of eventually producing a commercial product"³⁸⁶ Noncommercial experiments are defined to include research conducted by government, academic, and independent not-for-profit research organizations as long as the research is not intended for commercial use.³⁸⁷ An example of noncommercial research is research funded by unconditional gifts.³⁸⁸ EPA is also considering defining as commercial any application for an experiment accompanied by a request for protection of confidential business information.³⁸⁹

The EPA's attempt to divide scientific research into commercial and noncommercial categories may cause problems. According to a 1984 survey, private industry funds between sixteen and twenty-four percent of university research in biotechnology.³⁹⁰

385. See Statement of Policy, *supra* note 336, at 23,324. The EPA proposes to exclude certain uses of genetically engineered organisms containing intentionally introduced plant or animal gene segments from the general exemption, as well as certain uses of chemicals extracted from plants and animals. *Id.*

386. Toxic Substances; Revisions of Premanufacture Notification Regulations, Final Rule, 51 Fed. Reg. 15,096, 15,099 (1986).

387. Statement of Policy, *supra* note 336, at 23,331 (referring to Toxic Substances; Revisions of Premanufacture Notification Regulations, Final Rule, 51 Fed. Reg. 15,096, 15,098 (1986); Premanufacture Notification; Proposed Revision of Regulation, 49 Fed. Reg. 50,201, 50,205 (1984)).

388. 51 Fed. Reg. at 15,099. In its 1984 statement, the EPA was undecided whether to apply PMN reviews to purely academic or noncommercial field tests. The exemption would have hinged on the intent of the experimenters. "[P]urely academic field testing conducted for basic research" was to be exempt from regulation, whereas the testing of experimenters whose intent was commercial was to be regulated. 49 Fed. Reg. at 50,891. The EPA recognized that "[t]his may create an anomaly, because any risks associated with the field testing of a microorganism are independent of the commercial intent of the tester [but] RAC already provides considerable protection, and EPA believes it is appropriate for purely academic research to remain in the domain of the NIH." *Id.*

389. See *Planned EPA Proposal Would Require TSCA Reporting for All Company Research*, 10 CHEM. REG. REP. (BNA) 746, 746 (Sept. 12, 1986).

390. Blumenthal, Gluck, Louis & Wise, *Industrial Support of University Re-*

Thus, the EPA may have to determine whether a substantial amount of research is subject to regulation under TSCA. TSCA, however, was not designed to regulate basic research—whether commercial or noncommercial. The Act's legislative history specifies that academic and commercial research is exempt from regulation under TSCA.³⁹¹ The Act's language expressly exempts small quantities of chemical substances used for research and development from the premanufacture notification (PMN) requirement.³⁹²

Although private firms have demonstrated a willingness in the past to submit experiments to the RAC for review under the NIH Guidelines, it is likely that the EPA's assertion of jurisdiction over private research will be challenged in court, especially if the agency demands confidential data for its evaluation of proposed experiments. Another problem could occur if scientists conducting noncommercial research discovered commercial uses for

search in Biotechnology, 231 *SCIENCE* 242, 244 (1986).

391. The House version of section 5's exemption for scientific experimentation (which the conference committee adopted) was explicit in finding that the exemption applied to both academic and commercial research. The House report reads: "The exemption is necessary to insure that research and innovation, both academic and commercial, is not unduly impeded by the requirements of section 5." H.R. REP. No. 1341, 94th Cong., 2d Sess. 29 (1976). An ambiguity in the House committee's finding, when applying this exemption to rDNA technology, may come from the committee's conclusion that the "technically qualified individuals [manufacturing the substance] would be made aware of potential health and environmental effects [of the substance]." *Id.* Potential health and environmental effects are unknown in direct release experimentation involving genetically engineered organisms. Thus the rationale for the committee's conclusion is faulty when the exemption is applied to direct release experiments involving genetically engineered organisms.

392. 15 U.S.C. § 2604(h)(3) (1982). The conference committee on TSCA rejected a Senate proposal to apply section 5 of TSCA to experiments that had the potential for presenting an unreasonable risk of harm to the public health or the environment. H.R. CONF. REP. No. 1679, 94th Cong., 2d Sess. 64, 71-72, *reprinted in* 1976 U.S. CODE CONG. & AD NEWS 4539, 4549, 4556-57. The conference committee stated that TSCA "specifically exempt[s] from the notification requirements those chemical substances manufactured or processed . . . for scientific experimentation or analysis or for chemical research or analysis, including research and analysis for the development of the substance or another chemical substance into a commercial product." *Id.* at 71-72, *reprinted in* 1976 U.S. CODE CONG. & AD. NEWS at 4556-57. The only requirement in such cases is that people engaged in the experiment be notified of potential health risks. *Id.* at 72, *reprinted in* 1976 U.S. CODE CONG. & AD. NEWS at 4557.

their research after conducting unregulated direct release experiments. On a purely practical level, regulating experiments according to the intent of the researcher fails to address the essential reason why the regulations are needed: the potentiality of genetically engineered organisms to disperse and harm public health and the environment.

Another provision of TSCA implies that the statute would not apply to biotechnology research. The EPA can only require tests to be self-monitored by firms if "there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture . . . presents or will present an unreasonable risk of injury to health or the environment."³⁹³ Although "unreasonable risk" is not defined in TSCA,³⁹⁴ unless EPA can identify a specific risk, the agency may not be able to issue regulations requiring firms to self-monitor tests during research.³⁹⁵ An EPA official stated that "we would have to make a finding that there would be a possibility of significant risk [but] we think we can."³⁹⁶ Professor McGarity concurs, noting that because "unreasonable risk" implies a balancing process, courts would defer to EPA's decision because of the highly speculative nature of risks and benefits.³⁹⁷

393. 15 U.S.C. § 2605(a) (1982).

394. The Senate bill contained a definition of unreasonable risk identical to the definition in FIFRA, 7 U.S.C. § 136(bb) (1982). See 122 CONG. REC. 8291 (1976). The House committee deliberately excluded a definition, despite a suggestion that one be included. The House committee report stated: "Because the determination of unreasonable risk involves a consideration of probability, severity, and similar factors which cannot be defined in precise terms and is not a factual determination but rather requires the exercise of judgment on the part of the person making it, the Committee did not attempt a definition of such risk." H.R. REP. NO. 1341, 94th Cong., 2d Sess. 13-14 (1976). The House committee recommended that the EPA Administrator conduct an informal balancing test when deciding if an unreasonable risk existed. *Id.* at 14.

EPA "interpret[s] 'unreasonable risk' under TSCA to mean a situation in which a judgment is made that the probability and magnitude of harm to society of the use of a chemical are likely to outweigh the benefits." ENVIRONMENTAL PROTECTION AGENCY, PRIORITIES OF OTS OPERATION IV-7 (Jan. 1982).

395. See McGarity & Bayer, *supra* note 81, at 515-16.

396. *Environmental Implications Hearing*, *supra* note 147, at 155 (statement of D. Clay, Acting Assistant Administrator, Office of Pesticides and Toxic Substances, EPA).

397. *Potential Consequences Hearings*, *supra* note 121, at 126 (statement of T. McGarity, Professor of Law, University of Texas at Austin). See also R. DRULEY & G. ORDWAY, THE TOXIC SUBSTANCES CONTROL ACT 40 (rev. ed. 1981)

The EPA proposes amending the premanufacture notification (PMN) rule and perhaps the "significant new use" rule (SNUR) to exclude commercial direct release experiments from the general research and development exemption under TSCA.³⁹⁸ Genetically engineered organisms composed of intergeneric source organisms would thus be subject to the PMN requirement.³⁹⁹ Until the EPA begins rulemaking, researchers are requested to voluntarily report information ninety days in advance of proposed direct release experiments.⁴⁰⁰ Proposals for PMN review will be published in the *Federal Register*, and public comments invited.⁴⁰¹ Genetically engineered organisms with gene deletions are currently exempt from PMN requirements.⁴⁰² This is despite EPA's determination in 1984 that such organisms should be subject to PMN review because deletion could cause significant changes to an organism because of the potential for expression of other functions of the organism.⁴⁰³

("clear intent [of TSCA] is that a balancing approach be used in determining what constitutes an unreasonable risk").

398. Statement of Policy, *supra* note 336, at 23,330. See 15 U.S.C. § 2604(h)(3) (1982). A PMN is required under TSCA for all new chemical substances. *Id.* § 2604(a)(1)(A) (1982). See 40 C.F.R. §§ 720.3(cc), .36 (1986). A SNUR is required for the proposed significant new use of a chemical substance. 15 U.S.C. § 2604(a)(1)(B) (1982). See 40 C.F.R. §§ 721.615, .975 (1986).

399. Statement of Policy, *supra* note 336, at 23,325. An exemption is proposed for the transfer of genetic material composed only of well-characterized, noncoding regulatory regions. The EPA stated that this transfer is unlikely to result in a combination of significant new traits. *Id.* at 23,325-26. *But see Federal Policy Could Miss Full Review of Some Harmful Products, Scientists Say*, 10 CHEM. REG. REP. (BNA) 516, 516 (July 25, 1986). The EPA does not consider intragenetic organisms to be new. 51 Fed. Reg. at 23,326.

400. Statement of Policy, *supra* note 336, at 23,326. See 15 U.S.C. § 2604(a)(1) (1982). The EPA received the first voluntary application for PMN review in February 1987. The proposed experiment which will field test genetically engineered nitrogen fixation bacteria is being concurrently reviewed by the USDA under the FPPA. See Crawford, *Biotechnica Tests EPA Review Process*, 235 SCIENCE 840, 840 (1987).

401. Statement of Policy, *supra* note 336, at 23,327-28. See 15 U.S.C. § 2604(d) (1982). The EPA proposes using the Biotechnology Science Advisory Committee to review proposals. The potential for conflicts of interest in committee members reviewing proposals is recognized by the EPA, and steps are being taken to ensure that such conflicts do not occur. Statement of Policy, *supra* note 336, at 23,328.

402. Statement of Policy, *supra* note 336, at 23,325.

403. Proposed Policy, *supra* note 335, at 50,889. See generally Hardy, *Biotechnology in Agriculture: Status, Potential, Concerns*, in BIOTECHNOLOGY AND

Genetically engineered organisms that are pathogenic or contain genetic materials from pathogens will be subject to SNUR notification.⁴⁰⁴ EPA's regulations for SNUR review are basically the same as those for PMN review.⁴⁰⁵ Pathogenic genetically engineered organisms used only for agricultural purposes will be regulated by the USDA.⁴⁰⁶

Under authority of TSCA's reporting provision, the EPA requires anyone proposing a direct release experiment not subject to PMN or SNUR requirements to provide the agency with general information on the experiment. The information will be used to form a data base.⁴⁰⁷ If release of genetically engineered organisms causes substantial risk to human health or the environment, the experimenter is under a statutory duty to disclose information regarding the risk to the EPA.⁴⁰⁸ If data reported under the PMN or SNUR requirements does not indicate an unreasonable risk, however, the EPA has the burden of proof to show that the risk is unreasonable before it can prohibit the in-

THE ENVIRONMENT: RISK AND REGULATION 99, 103 (1985) ("[O]nly a small fraction of the hundred thousand or so genes that are in a plant cell are expressed or turned on at any one time, [and] we understand very little of how gene expression is turned on and turned off.").

Microbial pesticides with gene segment deletions are regulated under FIFRA. 40 C.F.R. § 158.65(b)(2) (1986). A proposal has been made to deregulate genetically engineered organisms with gene deletions or rearranged genes from NIH review. Notice of Proposed Actions Under NIH Guidelines for Research Involving Recombinant DNA Molecules, 51 Fed. Reg. 29,423, 29,423 (1986).

404. Statement of Policy, *supra* note 336, at 23,329.

405. *See id.*

406. *Id.* The EPA is deferring regulation of pathogenic genetically engineered organisms used solely for agricultural purposes to the USDA because EPA review of SNURs is discretionary under TSCA, whereas USDA review of plant pests is mandatory. *See id.*

407. *Id.* at 23,331. *See* 15 U.S.C. § 2607(a) (1982). The EPA is considering exempting small manufacturers from this requirement, consistent with the general exemption under TSCA from reporting for small manufacturers. Statement of Policy, *supra* note 336, at 23,331; *see* 15 U.S.C. § 2607(a) (1982).

The EPA has been developing a data base for PMN review of genetically engineered organisms since at least 1983. *See* Burckle & Venosa, *Environmental Engineering Research Support Proposal*, in RESEARCH NEEDS IN BIOTECHNOLOGY AND THE ENVIRONMENT C-1 (Nov. 1985).

408. TSCA only authorizes the EPA "to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment" 15 U.S.C. § 2601(b)(2) (1982).

roduction of genetically engineered organisms.⁴⁰⁹ Unless the EPA is able to quickly establish a predictive ecology data base, a problem could ensue. Data submitted with PMNs is notoriously sketchy,⁴¹⁰ and the current number of PMNs being reviewed by the EPA is about 1500 per year.⁴¹¹ The ninety-day period for review⁴¹² is inadequate under these conditions. Representative Florio predicts that under these circumstances the EPA will either accumulate a backlog of applications, or—more likely—fail to review them adequately.⁴¹³

The above discussion assumes the EPA's determination that a genetically engineered organism is a chemical substance or mixture is correct. Even if TSCA applies to genetically engineered organisms, however, hosts and vectors produced in the manufacturing process are not covered by the Act and therefore would not require a PMN. Thus, although a PMN may be required for the genetically manipulated DNA inside a host cell, one would not be required for the host cell itself.⁴¹⁴

Regulating biotechnology research under FIFRA and TSCA raises the problem of determining both risks and benefits. Risk-benefit analyses are inappropriate when discussing experiments in scientific research. FIFRA⁴¹⁵ and TSCA⁴¹⁶ are both risk-benefit

409. *Id.* § 2605(a) (1982).

410. See ENVIRONMENTAL PROTECTION AGENCY, FINAL REPORT ON BIOTECHNOLOGY WORKSHOP I: MAJOR ACCOMPLISHMENTS, FUTURE PLANS, AND IDENTIFICATION OF LIKELY IMPACTS FOR THE AGENCY 8 (Dec. 1983). In contrast to TSCA, FIFRA requires extensive data reporting. See 7 U.S.C. § 136a(c) (1982).

411. See Milewski, *supra* note 296, at 36.

412. 15 U.S.C. § 2604(a)(1) (1982).

413. See Representative James Florio, Remarks Before the Biotechnology Conference of the Brookings Institute 2 (Feb. 18, 1986); see also Note, *The EPA and Biotechnology Regulation: Coping with Scientific Uncertainty*, 95 YALE L.J. 553, 567 (1986) ("ninety-day provision prevents a meaningful decision about risk").

414. See generally McGarity, *supra* note 305, at 145.

415. See 7 U.S.C. § 136(bb) (1982) ("term 'unreasonable adverse effects on the environment' means any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide"). See generally Gelpe & Tarlock, *The Uses of Scientific Information in Environmental Decisionmaking*, 48 S. CAL. L. REV. 371, 417-19 (1974) (stating that court in *Environmental Defense Fund, Inc. v. Ruckelshaus*, 439 F.2d 584 (D.C. Cir. 1971), construed FIFRA to mandate "a comprehensive risk-benefit analysis" in accordance with EPA's construction of statute).

416. H.R. REP. No. 1341, 94th Cong., 2d Sess. 14 (1976) (defining "unreasona-

statutes. EPA regulates biotechnology under these statutes by "balanc[ing] between the restrictions and higher costs created by a regulation and the lower risks to public health and the environment"417 The potential risk of genetically engineered organisms (such as microbial pesticides) are thus compared with the benefits of the novel organisms replacing chemicals (such as chemical pesticides).418 Comparative risk analysis is vulnerable to substantial value judgments. The risks of traditional technologies are known, but potential risks of biotechnology are unknown and can be downplayed. Until the EPA is able to draw on a more extensive scientific data base,419 a risk-benefit analysis is inappropriate.

The conglomerate of laws, regulations, guidelines, and policy statements currently attempting to regulate biotechnology research is complex and confusing. Although the regulatory agencies are to be commended for attempting to regulate the products of biotechnology without a clear mandate from Congress, the agencies are ill-suited to regulate the scientific research behind those products. The NIH has over ten years of experience in regulating biotechnology experiments. Yet, at a time when that expertise is needed to address the significant increase in proposals for direct release experiments, the NIH's role has been reduced. Instead of allowing the regulatory confusion to worsen as the level of experiment proposals continues to increase, Congress should

ble risk" in TSCA as "balancing the probabilities that harm will occur and the magnitude and severity of that harm against the effect of proposed regulatory action on the availability to society of the benefits of the substance or mixture"). See *Toxic Substances Control Act Oversight: Hearings Before the Subcomm. on Toxic Substances and Environmental Oversight of the Senate Comm. on Environment and Public Works*, 98th Cong., 1st Sess. 18 (1983) (statement of D. Clay, Acting Assistant Administrator, Office of Pesticides and Toxic Substances, (EPA) (FIFRA and TSCA were written as risk-benefit statutes; thus balancing is the basis for each statute's regulatory system); see also Statement of Policy, *supra* note 336, at 23,328 (EPA economists are estimating risks and benefits of genetically engineered organisms to aid in regulatory decisions made under TSCA).

417. FIFTEENTH ANNUAL REPORT, *supra* note 95, at 465.

418. *Id.* at 465-66.

419. The Study Group on Biotechnology of EPA's Scientific Advisory Board found that the EPA needed more information on biotechnology, particularly regarding the dissemination, remedial actions, and environmental effects of genetically engineered organisms. SCIENCE ADVISORY BOARD, ENVIRONMENTAL PROTECTION AGENCY, ASSESSING EPA'S BIOTECHNOLOGY RESEARCH AND INFORMATION NEEDS: REPORT OF THE STUDY GROUP ON BIOTECHNOLOGY 4, 5 (1986).

address the issue of regulating research in biotechnology directly.

V. RECOMMENDATIONS

Scientists and regulators are faced with a dilemma in drafting regulations for biotechnology research. Risks may not exist, but their nonexistence is impossible to prove. The public, meanwhile, must not only be protected; it must believe that it is protected. Therefore, regulations must be drafted based on hypothetical risks. Although unnecessarily rigid regulations could stifle science, unnecessarily lax regulations may fail to prevent harm from occurring.⁴²⁰ Once in place, the regulations must be implemented publicly and effectively. The alternative is the loss of public confidence which has led residents in communities near proposed experiment sites to prevent experiments occurring by applying pressure for strict enforcement of local ordinances.⁴²¹

The Recombinant DNA Advisory Committee (RAC) began regulating DNA research when the process was contained in laboratories. The science's natural progression towards technological products rightfully involves regulatory agencies experienced in regulating commercial products.⁴²² Involvement of those agencies, however, should not preclude continuation of the RAC's expertise in regulating rDNA research. For other agencies to repeat the problems successfully faced by RAC over the past decade makes little sense.

The Coordinated Framework's attempt to fit regulation of biotechnology research under existing laws is ill-advised. The attempt invites judicial challenges,⁴²³ intra- and inter-agency juris-

420. See *Biotechnology Hearing*, *supra* note 235, at 2 (statement of Rep. Dingell) (rigid regulations can cause regulatory delays and stifle industrial development, but inadequate caution can result in judicial challenges and terrible disasters).

421. See Representative James Florio, Remarks Before the Biotechnology Conference of the Brookings Institute 5 (Feb. 8, 1986) (describing panic by residents near Monterey, California, experiment site despite two year review of proposed experiment by EPA).

422. See OFFICE OF TECHNOLOGY ASSESSMENT, *IMPACTS OF APPLIED GENETICS: MICRO-ORGANISMS, PLANTS, AND ANIMALS* 223 (1981) (describing limitation of Guidelines in regulating commercial applications and products).

423. See *supra* notes 308, 370-72, 391-97 and accompanying text; see also Wehr, *supra* note 330, at 3097 (citing EPA officials' belief that "agency's use of TSCA to regulate genetic engineering will almost certainly be challenged in

dictional disputes,⁴²⁴ potentially inflexible regulations,⁴²⁵ public distrust,⁴²⁶ and the forced uniform application of different statutory mandates.⁴²⁷ The existing laws were designed to regulate products, not scientific research.⁴²⁸ A statute designed specifically to regulate biotechnology research is necessary, not because the process of creating genetically engineered organisms may be unique, but because the public perceives it to be unique. The statute's purpose would be to provide a regulatory environment for biotechnology research that recognizes the unique problems involved in regulating scientific research while concurrently protecting public health, safety, and the environment. A new statute may necessarily be complex and lengthy. The alternative, however, is the Coordinated Framework's ninety-one pages of complex regulations, guidelines, and policy statements that threaten to expand as new rules are introduced by individual agencies.⁴²⁹

Although budgetary constraints argue against creating a new committee, the alternative is the regulation of biotechnology research by six federal agencies coordinated by the BSCC. Thus, if the Coordinated Framework continues as the vehicle to regulate biotechnology research, regulatory efforts of individual agencies will be duplicative. At the very least, rulemaking procedures will be duplicated. Within each agency, the money used to regulate biotechnology research will probably be drawn from other programs. This could reduce the effectiveness of programs from which funding was taken as well as committing inadequate funds to regulate biotechnology research. Funding problems will increase if the biotechnology industry grows as anticipated.

A committee modeled after the RAC would have a procedural and administrative framework in place. Original membership of

court").

424. See *supra* notes 300, 330 and accompanying text.

425. See *supra* notes 272, 311 and accompanying text.

426. See *supra* note 250 and accompanying text.

427. See *supra* notes 251-53 and accompanying text.

428. Cf. McGarity, *Contending Approaches to Regulating Laboratory Safety*, 28 U. KAN. L. REV. 183, 242 (1980) (arguing that because scientific research laboratories differ from industrial production processes, regulations written for industrial production should not be automatically applied "across the board to scientific research").

429. See, e.g., Statement of Policy, *supra* note 336, at 23,330 (EPA intends to amend TSCA regulations to cover regulation of genetically engineered organisms.).

the new RAC could be the same as for the existing RAC. This would ensure that the RAC's proven expertise would provide a solid cornerstone on which the new RAC could build. Continuation of the RAC by this means would also respond to the NIH's desire to withdraw from the regulation of direct release experiments as well as the desire of certain members of the RAC to continue regulating research.⁴³⁰ A change of jurisdiction for the RAC is preferable. Removing the RAC from the NIH, or creating a similar independent committee, would end the conflict between the NIH's promotional and regulatory functions.⁴³¹

The structure of the new RAC should remain essentially unchanged except that it would make decisions directly instead of advising the Director. Federal agencies and the public should be represented on the committee as before. The new committee and supporting staff could loosely resemble the CEQ,⁴³² except for the committee's larger size and status as an administrative agency. Members of the committee should be nominated as previously and should represent a multi-disciplinary mix of scientists plus lay people. The committee should have the power to convene subcommittees to review novel or controversial experiments or issues, as well as an independent scientific advisory panel authorized to conduct independent reviews of experiments and issues when appropriate. The ORDA, which should change jurisdiction to accompany the new RAC, should continue to provide support for the committee, publish the *Recombinant DNA Technical Bulletin*, and act as a clearing house for biotechnology.

The establishment of an independent agency would be pref-

430. *Compare Potential Consequences Hearing*, *supra* note 121, at 17 (statement of B. Talbot, Acting Director, National Institute of Allergy and Infectious Diseases, NIH) ("I think there are many at NIH who would look forward to our getting out of [regulating direct release experiments]") and *Planned Releases Hearing*, *supra* note 234, at 105-06 (statement of B. Crowley, Senior Associate Director, Resources, Community, and Economic Development Division, U.S. General Accounting Office) ("NIH wants to reduce its role and shift some of its responsibilities to agencies that are more directly involved in specific research matters.") with *Recombinant DNA Advisory Committee*, Minutes of May 3, 1985 meeting 29 (statement of W. Jolik, committee member) ("expanded use of working groups and subcommittees under RAC's purview would be much preferable to [Coordinated Framework]").

431. See OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 422, at 223 ("[r]egulation is not only foreign but antithetical to NIH's mission").

432. See 40 C.F.R. § 1515.3 (1986).

erable to adding biotechnology regulation to the mandate of an existing agency. As mentioned previously, the USDA not only suffers from an internal split in implementing regulations on biotechnology research, but is a major promoter of biotechnology research. The NIH also suffers from the conflict of promoting and regulating activities, and does not wish to continue regulating direct release experiments due to the agency's primary purpose in promoting biomedical research. The NSF is not a regulatory agency. Finally, the EPA's and FDA's traditions as regulators of commercial products do not aid those agencies in solving the unique problems associated with regulating scientific research.

The statute should create the new RAC, and give it broad and flexible authority to formulate procedures for all types of experiments involving biotechnology—public and private. Attempting to draw a line between commercial and noncommercial experiments, as proposed by the EPA, may prove difficult to administer because of the many varied relationships between universities and industry in biotechnology. As a practical matter, the same risks are posed whether experiments are commercial or noncommercial. The current NIH "Points to Consider" document for direct release experiments provides as much guidance as is currently feasible for preparation of direct release experiment proposals. The document should be adopted by the new RAC and modified whenever necessary as the science evolves.

The RAC's present procedures should be emulated as much as possible. The NIH Guidelines are the result of ten years' experience in regulating rDNA research. Procedures which should be duplicated include publication in the *Federal Register* of proposed changes in the guidelines, actions taken, and meetings to be held. On an individual level, experiments should proceed only after permits have been granted. Permits should be conditional, if appropriate, with a set duration. A permitting system with a suitable enforcement mechanism would be necessary for a comprehensive oversight of experiments.⁴³³ Provisions for public hearings near the site of proposed experiments, plus local representation on IBCs, would allow the new act to preempt the field, thus

433. See OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 422, at 234. Congressman Fuqua has proposed a three tier system for regulating biotechnology by providing for initial use permits, expanded use permits, and commercial use permits. See H.R. 4452, § 301(d)-(f), 99th Cong., 2d Sess. (1986).

resolving the problem of the potential enforcement of a myriad of state and local laws.⁴³⁴

To aid the new RAC in decision making, evolution of a scientific data base should be a priority.⁴³⁵ The committee's budget should include funding for risk assessment experiments and other necessary research. An experiment's site should be monitored before, during, and after experiments, with data to be reported to the new RAC. Submission of data is critical to building a data base in order to facilitate enforcement of regulations.⁴³⁶ Until a predictive ecology data base is formulated, permits should be issued on a case-by-case basis by the new RAC with review by local

434. See Comment, *Considerations in the Regulation of Biological Research*, 126 U. PA. L. REV. 1420, 1424-26 (1978), for a pro-federal preemption argument. In the past, residents of areas where experiments were scheduled have found enforcement of local laws to be the only means by which they were included in the decisionmaking process. For example, residents and public officials of Monterey County, California, were not consulted by the EPA despite that agency's grant of a permit to Advanced Genetic Sciences to conduct a direct release experiment in the county. County officials adopted an ordinance temporarily banning the experiment. See "Ice-Minus": A Case Study of EPA's Review of Genetically Engineered Microbial Pesticides, *Hearing Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 99th Cong., 2d Sess. 104-05 (1986) (comment of S. Karas, Chairman, Monterey Board of Supervisors).

435. One commentator has suggested that research into predictive ecology could be partially undertaken by requiring the research as a condition of accepting federal biotechnology grants. *Potential Consequences Hearing*, *supra* note 121, at 93 (statement of J. Doyle, Director, Agricultural Resources Project, Environmental Policy Institute). In late 1985 risk assessments were not even required for biotechnology research funded by the USDA. See *Planned Releases Hearing*, *supra* note 234, at 76 (statement of R. Colwell, Professor, Department of Zoology, University of California, Berkeley). However, research was beginning to be conducted on risk assessment technologies. See *id.* at 172 (statement of J. Jordan, Administrator, Cooperative State Research Service, USDA). For an analysis of risk assessment research funded by the NIH, NSF, USDA, EPA, and FDA, see UNITED STATES GENERAL ACCOUNTING OFFICE, *BIOTECHNOLOGY: ANALYSIS OF FEDERALLY FUNDED RESEARCH* (1986).

Another House bill, introduced by Congressman Fuqua, would establish a Biotechnology Science Research Program in OSTP to promote and coordinate public and private research. H.R. 4452, § 201, 99th Cong., 2d Sess. (1986). Congressman Fuqua's intent is to create a program similar to the nonprofit Health Effects Institute, which helped provide the scientific basis for regulations under the Clean Air Act. See 132 CONG. REC. H1303 (daily ed. Mar. 18, 1986) (statement of Rep. Fuqua).

436. See McGarity, *Legal and Regulatory Considerations in Environmental Biotechnology Applications*, 8 RECOMBINANT DNA TECHNICAL BULL. 1, 4 (1984).

IBCs. After a data base is in place, review of certain classes of direct release experiments could devolve to the relevant IBC in much the same way as the current NIH Guidelines categorize contained experiments. Care should be taken that IBCs have a broad spectrum of membership and that decisions are made as publicly as possible.⁴³⁷ Rather than exempt certain categories of experiments, case-by-case review by the new RAC, and subsequently by IBCs, should continue for the foreseeable future because of the limitless variety of environmental factors involved.⁴³⁸

Researchers should be required to post bonds and prepare plans for cleanup in the event inadvertent dispersal occurs.⁴³⁹ The committee should have authority to enforce compliance with its permit system, to monitor experiment sites and their environs, and to enforce cleanup orders. Penalties for noncompliance could include fines, or for particularly egregious violations, the subsequent denial of commercial permits to products developed from the process tested in the direct release experiment.⁴⁴⁰

Legislation emulating the extensive data requirements of FIFRA⁴⁴¹ may be needed in order to require proprietary data to

437. At the present time, some private firms include only people in their IBCs who are not expected to cause disruptions. *Biotechnology Development Hearing*, *supra* note 259, at 54 (statement of M. Lappe, Fellow, Hastings Center).

438. See *Planned Releases Hearing*, *supra* note 234, at 78 (statement of R. Colwell, Professor, Department of Zoology, University of California, Berkeley).

439. One method of remedying inadvertent dispersal that is currently being examined is to program suicide traits into genetically engineered organisms, e.g., making an organism heat sensitive so that the organism would die once a certain temperature was reached. See *Releasing Genetically Engineered Organisms Hearing*, *supra* note 336, at 28 (statement of J. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA).

Another factor, which would mitigate the impact of inadvertent dispersal of genetically engineered plants would be to require the plants to be susceptible to a specified herbicide. The herbicide could then be used in an emergency. See *Potential Consequences Hearing*, *supra* note 121, at 103 (statement of D. Simberloff, Department of Biological Science, Florida State University).

440. See Carr, *supra* note 300, at 11 (suggesting denial of permits or licenses to products violating USDA Guidelines); cf. Note, *Stopping a "Gruesome Parade of Horribles": Criminal Sanctions to Deter Corporate Misuse of Recombinant DNA Technology*, 59 S. CAL. L. REV. 641 (1986) (evaluating potential use of criminal sanctions as deterrent to corporate misuse of biotechnology).

441. 7 U.S.C. § 136a(c)(2) (1982). See *Ruckelshaus v. Monsanto*, 467 U.S. 986, 1007 (1984) (even though Monsanto had property interest in trade secrets voluntarily submitted to EPA, no taking occurred because registration conferred economic benefit on Monsanto, and conditions requiring data submission were ration-

be submitted to the new RAC. When the NSF attempted to create a biotechnology data base, the agency met with firm resistance from organizations even though most people contacted by the Foundation favored the data base's creation.⁴⁴² The proprietary nature of certain data could be preserved by presenting the data at closed meetings. Emphasis, however, should be on limiting the amount of confidential data as much as possible by use of the patent process.⁴⁴³

If possible, the new RAC should enjoy the same general exemption from NEPA as regulatory actions of the EPA. To attain this exemption, the statute should contain specifications to ensure that members of the committee include laypersons plus experts in ecology and epidemiology as well as molecular biology, and that review of experiments is public and thorough. The critical need is a full inquiry into the potential effects of the experiment not the procedures by which the inquiry is conducted.⁴⁴⁴

ally related to legitimate government interest).

442. H.R. REP. No. 44, 99th Cong., 1st Sess. 77 (1985). Many organization representatives contacted stated that they would not release information to the proposed data base unless they were assured that the information's further disclosure would be prohibited. *See id.* Indeed, many companies refused to disclose the areas in which they were conducting research or the personnel, costs, and objectives involved in the research. *Id.*

443. *See generally* McGarity, *supra* note 436, at 2-3 (companies preferring to protect their discovery under the category of trade secrets rather than patents should be required to justify decisions not to release data to public).

Protection can be gained by claims for patents for a genetically engineered microorganism or plasmid, a DNA sequence, or the "composition-of-matter" of a biologically introduced chemical compound. *See Withers, supra* note 129, at 673. Lesser protection may be gained by a patent claim for the "method of use" or "method of production" of the genetically engineered organism. *Id.*

A major disadvantage to patent protection is that a process protected by a United States patent may be used abroad, and the end product marketed freely in the United States. *See id.* at 674. A disadvantage in claiming a utility patent for the invention of a genetically engineered organism is the public recording of the invention, which may be used by a competitor to produce a modified microorganism, thereby avoiding infringement of the patent. *Id.* at 674-75. The complexity of the production of genetically engineered organisms makes enforcement of the patent laws difficult. *Id.* at 675. *See also* Abramson, *supra* note 354, at 699-700 (suggesting amendment to FIFRA to protect preregistration data on pesticides). For a discussion of the potential application of copyright protection to genetically engineered organisms, see Kayton, *Copyright in Living Genetically Engineered Works*, 50 GEO. WASH. L. REV. 191 (1982).

444. *See* Bazelon, *supra* note 188, at 1069 ("[I]t is not the procedures but the fullness of the inquiry that is paramount.").

Exemption from NEPA would eliminate the potential requirement of a programmatic EIS and its inherent balancing of benefits and risks, which are too speculative to be quantified at this stage of scientific research.

Congress has decided—albeit by default—that biotechnology experimentation should continue. A discussion of alternatives to conducting experiments would, therefore not be beneficial. The alternative of no action, or of imposing a moratorium, would not be helpful. Direct release experiments have already occurred.⁴⁴⁵ Limiting experiments by permitting an arbitrary number to take place is not practicable because of the diversity of experiments using biotechnology. It would not be feasible to dictate the type of experiments which were to take place or the number of each type. Proposals for specified experiments may not be submitted, or proposed experiments may prove to be scientifically inadequate. Meanwhile, other proposals could be delayed because they were not on the new RAC's list of experiments to be approved. In addition, unless experiments are allowed to proceed, the scientific data base on which to base regulation of biotechnology products will be severely limited.⁴⁴⁶

The new RAC should use risk assessment/risk management as an analytical tool. This procedure is used extensively by federal agencies for regulating environmental and health risks.⁴⁴⁷

445. In addition to the illegal direct release experiment in Oakland, California, an experiment approved by USDA, the NIH, and the Wisconsin Department of Natural Resources was conducted in May/June 1986. The experiment involved planting tobacco plants into which disease resistant genes had been transferred. The experiment was conducted to test the tobacco plants as a model, and not for commercial reasons. Sun, . . . *While First Outdoor Test of Engineered Plant Begins*, 232 *SCIENCE* 1340, 1340 (1986).

446. See *Potential Consequences Hearing*, *supra* note 121, at 87 (statement of D. Jackson, Senior Vice President and Chief Scientific Officer, Genex Corp.).

447. The study of risk assessment and risk management relating to biotechnology was on the agenda of the Interagency Risk Management Council before its demise and subsequent replacement by the interagency risk assessment panel of the OSTP and NSF. See *White House Science Group Sets Agenda for Review of Risk Assessment Practices*, 16 *ENV'T REP. (BNA)* 724, 724 (1985); *Cancer Policy, Formaldehyde Regulation, Biotechnology Occupy New Interagency Group*, 14 *ENV'T REP. (BNA)* 1920, 1920 (1984).

Before its demise the Interagency Risk Management Council published an interim report on cancer risk assessment. Similarly to biotechnology regulation, different agencies regulate carcinogens under a variety of statutes. See generally Note, *Environmental Carcinogenesis: Regulation on the Frontiers of Science*, 7

Risk assessment should be bifurcated from risk management procedurally but not separated organizationally.⁴⁴⁸ The risk assessment process should have as few legal restraints as possible to ensure maximum discretion in protecting the public from risks. Results of risk assessments should be published in the *Federal Register* and *Recombinant DNA Technical Bulletin*. Comments should be encouraged, and scientific advisory panels appointed if deemed necessary by the committee.

The risk management process should be more structured than the risk assessment process, involving notice, comments, and public hearings. Public hearings should be held in the locale where the experiment would take place. Hearings should not be adversarial in nature, but should attempt to approximate scientific review of proposals.⁴⁴⁹ At this early stage in research, the party with the burden of proof would almost assuredly lose. Regulators could not prove that a risk existed; researchers could not prove that a risk was nonexistent.

These recommendations for a unified policy for regulating biotechnology experiments do not purport to preclude regulation of products of biotechnology by federal agencies. The recommendations do purport to preclude regulation of scientific processes in biotechnology research by any committee other than the new

ENVTL. L. 83 (1976) (discussing regulatory framework governing environmental carcinogens). The interim report stated that an interagency guideline on cancer risk assessments should not be devised because of the various agencies' statutory responsibilities in regulating carcinogens and the scientific uncertainty involved in the risk assessment. In contrast to the report—and echoing the rationale behind the Coordinated Framework for Biotechnology—White House science policy advisors advocated formulating a single document in which disputed regulatory and scientific issues would be interpreted. See *Codifying Hazard Evaluation Practices Ill-Advised, Interagency Panel Concludes*, 16 ENV'T REP. (BNA) 558, 558-59 (1985).

448. Four federal regulatory agencies were questioned by a congressionally mandated committee about a proposal to organizationally separate risk assessment from regulatory policymaking. The main arguments against the proposal were: (1) separation would not result in isolating science from policy; and (2) political acceptability and accountability would be lost by dividing responsibility for the decisions. RISK ASSESSMENT IN THE FEDERAL GOVERNMENT, *supra* note 91, at 139-40.

449. See Ebner, *supra* note 330, at 41 (EPA recognized by early 1980s that adjudicatory proceedings were an inappropriate forum for eliciting scientific data on risks and benefits).

RAC, and to limit jurisdiction of the new RAC to regulation of scientific processes.